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cc:

Subject: RESPONSE TO COMMENTS - PINE CHEMICALS ASSOCIATION

Please find attached the Pine Chemicals Association's HPV Task Force's response to ,EPA, ED and PETA comments concerning our Test Plan for fatty Acid Dimersand Trimer.

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 - DimerResponseLetter1.11.doc

October 28, 2002

The Honorable Christine Todd Whitman
Administrator
U.S. Environmental Protection Agency
P.O. Box 1473
Merrifield, VA 22116

Attention: Chemical Right-to-Know Program

Re: Response to Comments and Amendments to Pine Chemicals Association, Inc. Test Plan for Fatty Acid Dimers and Trimer

Dear Ms. Whitman:

The Pine Chemicals Association, Inc. (PCA) HPV Task Force is pleased to submit its response to comments received on its March 2002 Test Plan for Fatty Acid Dimers and Trimer. We have carefully reviewed the comments submitted by the Environmental Protection Agency (EPA), the Environmental Defense (ED) and the People for the Ethical Treatment of Animals (PETA) in July 2002. This document responds to those comments and amends our March 2002 Test Plan. We have organized the submission by subject matter in the same order as our Test Plan.

RESPONSE TO COMMENTS & AMENDMENTS TO TEST PLAN

Categorization of Substances / Selection of Test Material

PCA proposed to group four substances in its Test Plan for Fatty Acid Dimers and Trimer. Under this Test Plan, PCA proposed to use dimer (CAS # 61788-89-4) as the category representative. All of the commenters agreed with the establishment of the category, as well as using dimer as the category representative.

ED requested that PCA provide further information on the concentration ranges of the various constituents of the category substances. Specifically ED requested information on the ranges of acylic dimer, cyclic dimer, aromatic dimer and polycyclic dimer and suggested that "there certainly must be guidelines for acceptable percentages of the various constituents for quality control." ED is correct that there are certain parameters used for quality control, albeit different ones than those suggested by ED. They include the percentage ranges of monomer, dimer and trimer as determined using GPC methodology, as well as viscosity, color and acid number. PCA notes that this information was previously

provided in the Test Plan which listed the concentration ranges of dimer, trimer, and hydrogenated dimer in a typical dimer product (the same constituents used for quality control considerations).

Physicochemical Data

PCA stated in its Test Plan that it would not determine melting point, boiling point, and vapor pressure due to the physical characteristics of the substances. EPA, however, "believes that the submitter can get measured/estimated values for these endpoints for representative substances." We note that we are unsure why EPA believes that measurement/estimation of these values is appropriate for the substances in the dimer category, since EPA previously agreed that the measurement/estimation was not appropriate for the substances in the rosin adducts category "for purposes of the HPV Program". These endpoints are not appropriate or feasible for measurement or estimation for this category of substances for several reasons:

- Melting Point – Consistent with Class 2 substances, these substances do not have a sharp melting point. Upon cooling, these substances will first become cloudy, turn into a slurry and then solidify/crystallize over a broad range of temperatures. Thus, melting points have no significance for these substances.
- Boiling Point - A boiling point at ambient pressure is not possible since at ambient pressure, these substances will thermally decompose before they boil.
- Vapor Pressure - Vapor pressures for these substances are effectively zero at ambient temperatures, and their experimental measurement is inappropriate.

In addition, we note that EPA's recommendation that these parameters be measured or estimated for "representative substances" is not relevant for the substances in this category. All four substances in this category are large molecules and none of the constituents of these complex mixtures can be reasonably considered as representative of the mixture (i.e., the specific substance) itself.

Environmental Fate - Photodegradation and Fugacity

PCA stated in its Test Plan that it would not measure photodegradation, hydrolysis, or fugacity (transport and distribution). Although EPA agreed with PCA's explanation concerning hydrolysis, EPA suggested that photodegradation and the other required inputs can be "measured/estimated" so that a fugacity model could be run. PCA again notes that it is uncertain why EPA disagrees

with the rationale stated in the Dimers Test Plan, since it agreed with the same logic in the Rosin Adducts Test Plan. As stated in the Dimers Test Plan, measurement of photodegradation and fugacity is not appropriate for these Class 2 substances:

- Photodegradation - Due to their lack of vapor pressure under ambient conditions, there is essentially no opportunity for these substances to enter the atmosphere; thus photodegradation is not relevant.
- Fugacity - Fugacity can not be modeled since several of the required inputs are not feasible to determine (e.g., molecular mass, reaction half-life estimates for air, water, soil, sediment, aerosols, suspended sediment.)

Accordingly, PCA will not amend its Test Plan with respect to these endpoints.

Ecotoxicity Tests

EPA agreed with the proposed acute toxicity testing of fish, daphnia and algae on dimer, but disagreed with how the tests should be conducted. More specifically, EPA recommended that the tests be done at pH 7 and disagreed with using filters, centrifugation, or water-accommodated fractions of the test substance. PETA, on the other hand, suggested that PCA forego aquatic toxicity testing and use another method, such as ECOSAR or TETRATOX. With respect to the latter suggestion, it should be noted that neither of these models has been recognized as part of the SIDS or HPV program.

As an initial matter, it appears that EPA incorrectly believes that dimer salts are part of this category when, in fact, they are not. EPA was concerned that these substances have an inherent tendency to form an aqueous milky dispersion, emulsion, or critical micelles and noted that the soluble salts of these chemicals should be dispersible in water just as surfactants and detergents are dispersible in water. Similarly, EPA commented that "when testing, the overall test substance concentrations should not exceed the dispersibility limit or the critical micelle concentration. The test substance solubility should not be viewed as a water solubility limit." Although salts of the category substances may form micelles, the dimers and trimer in this category, as non-salts, will not form micelles.

As noted above, EPA commented on several aspects of the methodology discussed in our Test Plan. After reviewing the comments, PCA believes that EPA's concerns can be addressed without amending the Test Plan. In the Test Plan, PCA stated that ecotoxicity testing would be conducted under conditions that maximize solubility, but reduce exposure to insoluble fractions. The methodology for preparing the water for PCA's ecotoxicity testing of dimer is

identical to that used to determine the solubility of this substance. This procedure was adopted in order to ensure that ecotoxicity testing was conducted at the limit of actual water solubility. EPA's comment that "the test substance solubility should not be viewed as a water solubility limit" may be true in some instances, but does not appear to be accurate with respect to dimer. Since the method used to maximize the solubility of dimer for the determination of water solubility was essentially identical to the method used for ecotoxicity testing, this process does, in fact, determine the limit of water solubility.

EPA commented that the ecotoxicity tests should be run at pH 7. We note that OECD protocols for ecotoxicity testing (as well as OECD's guidance for difficult to test substances) do not require a specific pH of 7 and that all testing will be consistent with such protocols and guidance. The Agency also stated that it disagreed with using filters, centrifugation, or water-accommodated fractions (WAF) of the test substance. However, a careful reading of the test plan would reveal that preliminary testing to investigate the effects of filtering and adjusting pH would be undertaken to minimize nonspecific physical effects (an approach that was endorsed by EPA in comments on other test plans). Only if such exploratory testing revealed that these procedures influenced potential toxicity would they be used in the definitive test. The Dimer Test Plan never mentioned centrifugation. We note that the use of WAF as well as filtration are both methods that are recommended for difficult to test substances (OECD 2000).

Finally, as noted above, EPA suggested that the chemical should be tested as manufactured. Because the protocol that will be used to prepare water samples for ecotoxicity testing is identical to the protocol used to measure water solubility, this is precisely the manner in which ecotoxicity testing on dimer will be conducted, i.e., as manufactured.

Human Health Effects

In the Test Plan, PCA noted the availability of data on dimer for all HPV health effects endpoints except developmental, for which we proposed to conduct OECD 421 (combined reproductive/developmental testing). All commenters agreed that the available data were adequate, although ED recommended that a combined reproductive/developmental test should be performed for several reasons. PETA, on the other hand, suggested that PCA perform an *in vitro* test for embryotoxicity testing known as the rodent Embryonic Stem Cell Test (EST).

After consideration of these comments, PCA does not intend to amend its test plan and perform *in vitro* testing. Although we recognize that this methodology has been validated by the European Centre for the Validation of Alternative Methods, neither OECD nor EPA has incorporated this test into their

developmental toxicity testing guidelines, nor has EPA endorsed its use in the HPV Program. PCA, therefore, respectfully declines to use this *in vitro* protocol, and instead will use the OECD 421 test method as described in the test plan. Since OECD 421 addresses both developmental and reproductive effects, ED's concerns should be addressed under the current proposal.

EPA also suggested that a robust summary of the developmental, as well as reproductive endpoints, should be provided. We intend to provide a robust summary for all of the testing results.

* * *

PCA appreciates the comments from EPA, ED and PETA, as well as the opportunity to respond. We look forward to sharing the data generated pursuant to the Test Plan.

Respectfully submitted,

Walter L. Jones
President & COO